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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/687,951	10/13/2000	Jeffrey L. Cleland	GEN02-002-US	8871
23552	7590	01/03/2006	EXAMINER	
MERCHANT & GOULD PC P.O. BOX 2903 MINNEAPOLIS, MN 55402-0903			KAM, CHIH MIN	
			ART UNIT	PAPER NUMBER
			1656	
DATE MAILED: 01/03/2006				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/687,951

Applicant(s)

CLELAND ET AL.

Examiner

Chih-Min Kam

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 November 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 20, 22, 23, 25-31, 33, 34, 36 and 40-44 is/are pending in the application.
- 4a) Of the above claim(s) 44 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 20, 22, 23, 25-28, 30, 31, 34 and 40-43 is/are rejected.
- 7) ☒ Claim(s) 29, 33 and 36 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>11/23/05</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. The Request for Continued Examination (RCE) filed on November 23, 2005 under 37 CFR 1.114 is acknowledged. An action on the RCE follows.

Status of the Claims

2. Claims 20, 22-23, 25-31, 33-34, 36 and 40-44 are pending.

Applicants' amendment filed on November 23, 2005 is acknowledged, and the response has been fully considered. Claims 20, 22-23, 25-28, 30-31 and 33-34 have been amended, claims 17, 21, 35 and 37-39 have been cancelled, and new claims 40-44 have been added. Newly submitted claim 44 directed to an invention that is distinct from the invention originally claimed for the following reasons:

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claim 44 is withdrawn from consideration as being directed to a nonelected invention. See 37 CFR 1.142(b) and MPEP § 821.03. Thus, claims 20, 22-23, 25-31, 33-34, 36 and 40-43 are examined.

Withdrawn Claim Rejections - 35 USC § 102

3. The previous rejection of claims 17, 21, 23, 25-29, 34, 35 and 39 under 35 U.S.C. 102(e) as being anticipated by Cleland *et al.* (US Patent 6,113,947, filed June 13, 1997), is withdrawn in view of applicants' cancellation of the claims, applicant's amendment to the claim, and applicants' response at pages 5-6 in the amendment filed November 23, 2005.
4. The previous rejection of claims 17, 21, 23, 25-28, 34 and 39 under 35 U.S.C. 102(e) as being anticipated by Suzuki *et al.* (US Patent 6,197,326, filed October 14, 1998), is withdrawn in

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view of applicants' cancellation of the claims, applicant's amendment to the claim, and applicants' response at page 6 in the amendment filed November 23, 2005.

Withdrawn Claim Rejections - 35 USC § 103

5. The previous rejection of claims 17, 20, 21, 23, 25-29, 34, 35 and 39 under 35 U.S.C. 103(a) as being unpatentable over Cleland *et al.* (US Patent 6,113,947) in view of syringe section (page T515) of Aldrich catalog (1996-1997), is withdrawn in view of applicants' cancellation of the claims, applicant's amendment to the claim, and applicants' response at pages 6-8 in the amendment filed November 23, 2005.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 20, 22, 28, 30, 31 and 40-43 are rejected under 35 U.S.C. 102(b) as being anticipated by Tsunenaga *et al.* (US Patent 5,137,875, published August 11, 1992).

Tsunenaga *et al.* teach an aqueous solution or aqueous dispersion of collagen in hyaluronic acid for internal injection into mammals (column 2, lines 52-68), where a mixed dispersion having a glutaraldehyde-crosslinked atelocollagen with particle size of 50 to 100 μm at a concentration of 7.5% (corresponding to 75 mg/ml; claims 28, 30, 31) and a hyaluronic acid concentration of 0.5% in phosphate buffer at pH 7.3 and an osmolality of 320 mOsm/kgH₂O is obtained (Example 6; claims 20, 22 and 40-43). Since collagen is a protein abundant in skin, blood vessel, cornea, tendons, bones and teeth of animals, and purified collagen can be used as

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local hemostatics, artificial skin or eardrums, and contact lenses (column 1, lines 20-29), thus collagen is a biologically active agent and also a biocompatible polymeric matrix, which meets the criteria of the claimed invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 20, 22, 23, 25-28 and 34 are rejected under 35 U.S.C 103(a) as being unpatentable over Suzuki *et al.* (US Patent 6,197,326, filed October 14, 1998).

Suzuki *et al.* teach an intra-articular preparation for the treatment of arthropathy, which comprises microcapsules of a biocompatible, high molecular weight substance such as PLGA, homopolymer or copolymer of lactic acid, glycolic acid, caprolactone and others (column 1, lines 45-60; column 2, line 66-column 3, line 30; claims 25-27), and a drug such as steroid agents, cyclosporin (a cyclic peptide; column 3, lines 44-64; claims 28); and the microcapsules can be administered in the form of injection by suspending it in a dispersion medium, where injection-grade water may be used as the dispersion medium, further, a buffer, an isotonicity (e.g., NaCl; claim 23), and others can be added, particularly a microcapsule-dispersing medium which contains hyaluronic acid, or chondroitin sulfate or salts thereof is particularly preferred (column 4, line 60-column 5, line 8; claims 20, 22 and 34). Although the reference does not specifically teach the concentration of hyaluronic acid in buffer for the formulation, the reference suggests the use of hyaluronic acid as a microcapsule-dispersing medium and the addition of a buffer

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when it is needed for injection, thus it would be obvious to use a proper amount of hyaluronic acid in buffer to maintain the suspension of microcapsules for injection, which results in the claimed invention and was, as a whole, prima facie obvious at the time the claimed invention was made.

Claim Objections

8. Claims 29, 33 and 36 are objected to as being dependent upon a rejected base claim.

Conclusion

9. Claims 20, 22, 23, 25-28, 30, 31, 34 and 40-43 are rejected, and claims 29, 33 and 36 are objected to.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (571) 272-0948. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Kerr can be reached at 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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Chih-Min Kam, Ph. D.

Patent Examiner

A handwritten signature in black ink, appearing to read 'Chih-Min', followed by a long horizontal stroke.

CHIH-MIN KAM
PATENT EXAMINER

CMK

December 22, 2005